Detailed guidance explains excise tax on post-2012 medical device sales, provides transition relief-Dec.6, 2012

IRS has issued final regs on the Code Sec. 4191 excise tax on post-2012 sales of medical devices, which was enacted by the Health Care and Education Reconciliation Act of 2010 in conjunction with the Patient Protection and Affordable Care Act (jointly, the ACA). The regs, which apply to the sale of taxable medical devices after Dec. 31, 2012, affect manufacturers, importers, and producers of such devices. At the same time, IRS issued a Notice providing interim guidance on determining "price" for medical excise tax purposes, the tax treatment of medical kits, and transition relief for device manufacturers from failure to deposit penalties for the first three quarters of 2013. A series of accompanying Q&As cover mechanics of the excise tax.

Background. For sales after Dec. 31, 2012, a tax equal to 2.3% of the sale price is imposed on the sale of any taxable medical device by the manufacturer, producer, or importer of such device. (Code Sec. 4191(a)) A taxable medical device is any device defined in § 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) that's intended for humans. (Code Sec. 4191(b)(1)) Section 201(h) of the FFDCA defines "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article. This includes any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease; or (3) intended to affect the structure or any function of the body, and which does not achieve its primary intended purposes through chemical action within or on the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Code Sec. 4191(b)(2) provides that a "taxable medical device" does not include eyeglasses, contact lenses, hearing aids, or "any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use" (retail exemption).

Under Code Sec. 4221, certain sales are exempt from the tax imposed under Chapter 32 (dealing with manufacturers excise taxes). The Reconciliation Act amended Code Sec. 4221 to limit the exemptions for taxable medical device sales to sales by the manufacturer, producer, or importer: (1) for use by the purchaser for further manufacture, or for resale by the purchaser to a second purchaser for use by such second purchaser in further manufacture; or (2) for export, or for resale by the purchaser to a second purchaser for export.

In late 2010, IRS issued Notice 2010-89, 2010-52 IRB 908, requesting comments on the implementation and administration of the new tax (see Weekly Alert ¶ 7 12/09/2010).

And earlier this year, IRS issued proposed regs (Weekly Alert ¶ 19 02/09/2012). Now IRS has finalized the proposed regs with some changes.

Definition of "taxable medical device." The final regs provide that for purposes of the medical device excise tax, a device defined in section 201(h) of the FFDCA that is intended for humans means a device that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR Part 807, pursuant to FDA requirements. Devices that the FDA Center for Biologics Evaluation and Research (CBER) regulates that are not listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807, such as biologics that are listed under 21 CFR part 607, are not taxable medical devices.

IRS rejected suggestions that (1) devices that have medical and non-medical applications, and (2) certain devices used in connection with rare diseases, be excluded from the excise tax. However, IRS did agree that software and software updates that are not required to be separately listed with the FDA do not fall within the definition of a taxable medical device, and sales of such software and software updates are not subject to the tax.

Intended for humans. The final regs say a device defined in section 201(h) of the FFDCA that is intended for humans means a device that is listed as a device with the FDA under section 510(j) of the FFDCA and 21 CFR part 807, pursuant to FDA requirements. IRS rejected suggestions that the phrase "intended for humans" distinguished between devices intended for use directly on patients or directly in patient care from other devices (such as sterilization process indicators and containers) that are otherwise used in human medicine.

Retail exemption. Under the final regs, a taxable medical device does not include any device of a type that is generally purchased by the general public at retail for individual use. A device meets the retail exemption if (a) it is regularly available for purchase and use by individual consumers who are not medical professionals, and (b) the design of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional. The relevant facts and circumstances determine whether a device meets this dual test. Additionally, there may be facts and circumstances that are relevant in evaluating whether a device is of a type generally purchased by the general public at retail for individual use in addition to those enumerated in the regs.

The determination of whether a device is of a type that qualifies for the retail exemption is made based on the overall balance of factors relevant to the particular type of device. The fact that a device is of a type that requires a prescription is not a factor in the determination of whether or not the device falls under the retail exemption.

Regularly available for purchase and use by individual consumers. The following factors are relevant in determining whether a device is of a type that is regularly available for purchase and use by individual consumers who are not medical professionals:

1. Whether consumers who are not medical professionals can buy the device in person, over the telephone, or over the internet, through retail businesses such as drug stores, supermarkets, or medical supply stores and retailers that primarily sell devices (for example, specialty medical stores, suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and similar vendors);
2. Whether consumers who are not medical professionals can use the device safely and effectively for its intended medical purpose with minimal or no training from a medical professional; and
3. Whether the device is classified by the FDA under Subpart D of 21 CFR part 890 (Physical Medicine Devices).

Primarily for use in a medical institution or office or by a medical professional. The following factors are relevant in determining whether a device is designed primarily for use in a medical institution or office or by a medical professional:

1. Whether the device generally must be implanted, inserted, operated, or otherwise administered by a medical professional;
2. Whether the cost to acquire, maintain, and/or use the device requires a large initial investment and/or ongoing expense that is not affordable for the average individual consumer;
3. Whether the device is a Class III device under the FDA system of classification;
4. Whether the device is classified by the FDA under various 21 CFR definitions, for Clinical Chemistry and Clinical Toxicology Devices, Hematology and Pathology Devices, Immunology and Microbiology Devices, Anesthesiology Devices, Cardiovascular Devices, Ear, Nose, and Throat Devices, Gastroenterology - Urology Devices, General and Plastic Surgery Devices, Neurological Devices, Ophthalmic Devices, Orthopedic Devices), Radiology Devices, Dental Devices; Obstetrical and Gynecological Devices); or Physical Medicine Devices; and
5. Whether the device qualifies as DMEPOS for which payment is available exclusively on a rental basis under the Medicare Part B payment rules, and is an “item requiring frequent and substantial servicing” as defined in 42 CFR 414.222.

A safe harbor in the regs provides a technical definition of a number of devices that are treated as being of a type generally purchased by the general public at retail for individual use. These include certain prosthetics, orthotics, therapeutic shoes, and supplies necessary for the effective use of durable medical equipment.

Kits. In general, a convenience kit is two or more different medical devices, or a combination of medical devices and other items, packaged together for the convenience of the user. Notice 2012-77, says that IRS is studying the taxability of convenience kits and intend to issue additional guidance in the future. Until IRS issues further guidance, no tax will be imposed upon the sale of a

domestically-produced convenience kit that is a “taxable medical device” under Code Sec. 4191 and Reg. § 48.4191-2(b) . During this interim period, Notice 2012-77, provides that the sale of a taxable medical device that goes into a domestically-produced convenience kit will be subject to tax upon its sale by the manufacturer or importer, pursuant to the normal rules of Code Sec. 4191 and the regs thereunder; however, the sale of the convenience kit by the kit producer will not be subject to tax.

Additionally, until the IRS issues further guidance, tax is imposed under Code Sec. 4191 and Reg. § 48.4191-2(b), on the sale by an importer of a convenience kit that is a taxable medical device, but only on that portion of the importer's sale price of the convenience kit that is properly allocable to the individual taxable medical devices included in the convenience kit.

Hospitals or medical institutions that produce kits for their own use are known as self-kitters. Such self-kitters are exempt from the FDA's registration and listing requirements. As a result, under the definition of a taxable medical device in the regs, a kit produced by a hospital or medical institution for its own use is not a taxable medical device, and the use of the self-produced kits by the hospital or medical institution is not a taxable use under Code Sec. 4218. (Preamble to TD12/05/2012)

Determination of price. The Code Sec. 4191 excise tax is 2.3% of **the price** for which the taxable medical device is sold. Notice 2012-77, provides detailed interim rules for determining price for medical excise tax purposes in a number of settings, such as sales to unrelated retailers, related retailers, related resellers, and sales to hospital or doctors' offices.

Deposit penalty relief. The medical device excise tax is a manufacturers excise tax reported on Form 720 (Quarterly Federal Excise Tax Return). IRS recognizes that many medical device manufacturers will still be preparing their systems to comply with the medical device excise tax when the tax goes into effect on Jan. 1, 2013, including the requirement to make semimonthly deposits. The first deposit of the medical device excise tax, covering the first 15 days of January, is due by Jan. 29, 2013. In consideration of the short time frame between the effective date of the tax and the due date of the first deposit, and in the interest of sound tax administration, IRS has decided to provide temporary relief from the Code Sec. 6656 penalty (for failure to make timely deposits of tax as required by Code Sec. 6302) for the first three calendar quarters of 2013.

Specifically, under Notice 2012-77, IRS will not impose the Code Sec. 6656 penalty on a taxpayer that is liable for the medical device excise tax that fails to make timely deposits of the medical device excise tax, provided that the taxpayer demonstrates a good faith attempt to comply with requirements of Reg. § 40.6302(c)-1 and Reg. § 40.6302(c)-2 and that the failure was not due to willful neglect. Thereafter, a taxpayer may avoid penalties if it makes an affirmative showing that the failure to deposit is due to reasonable cause and not due to willful neglect. In addition, during the third and fourth calendar quarters of 2013, IRS will not exercise its authority under Reg. § 40.6302(c)-1(b)(2)(v), to withdraw the taxpayer's right to use the deposit safe harbor rules of Reg. § 40.6302(c)-1(b)(2)ii)